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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/075,635	02/13/2002	Constantin Agouridas	146.1327-CON	9887

7590 05/04/2004

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EXAMINER

COLEMAN, BRENDA LIBBY

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 05/04/2004

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/075,635

Applicant(s)

AGOURIDAS ET AL.

Examiner

Brenda Coleman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☒ Certified copies of the priority documents have been received in Application No. 09/416,022.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claims 1-13 are pending in the application.

Specification

1. The disclosure is objected to because of the following informalities: The pages of the specification including claims and abstract must be numbered consecutively, starting with 1, the numbers being centrally located above or preferably, below, the text.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

2. Claims 1-4 and 7-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

- a) Claims 1-4 and 8-11 are vague and indefinite in that it is not known what is meant by the moiety $\text{-C(=O)-Ar}_2\text{OR-(CH}_2\text{)}_n\text{-Ar}$.
- b) Claim 7 is vague and indefinite in that the last species contains a close parenthesis, which is unmatched. See line 16 of the claims.
- c) Claim 7 is vague and indefinite in that it is not known what is meant by the nomenclature of the second species, which has a hash mark through the 17 of 17-hydroxymethyl in line 16 of the claim and an 18 hand written above it.
- d) Claims 7, 9 and 11 are vague and indefinite in that the nomenclature of the second species contains several typographical errors, i.e. [3aS-(3aR*, 4S*,

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7R*, 9S*, 10S*, 11S*, 13A*, 15S*, 15aS*, 17R*)]-4-ethyl-7-fluoro-3a, 4, 10, 11, 12, 13, 15, 15a-octahydro-18-hydroxymethyl)-11-methoxy-3a, 7, 9, 11, 13, 15-hexamethyl-10-[[3-4,6-trideoxy-3-(dimethylamino)-.beta.-D-xylohexopyranosyl]oxy]-14,1-(nitriloethano)-2H-oxacyclotetradecino[4,3-d]oxazole-2,6,8(9H)-trione. It is believed that this species is example 2 where the following items appear:

- 1) 3aR* appears but is not present in example 2 on pages 14-15;
 - 2) 4S* is 4R in example 2;
 - 3) 7R* is 7S in example 2;
 - 4) 9S* is 9R in example 2;
 - 5) 10S* is 10R in example 2;
 - 6) 11S* is 11R in example 2;
 - 7) 13A* is 13R in example 2;
 - 8) 15S* is 15R in example 2;
 - 9) 15aS* is 15aR in example 2;
 - 10) 17R* is 18S in example 2;
 - 11) a hyphen appears between 3 and 4 in 3-4,6-trideoxy;
 - 12) there is a hyphen missing between xylo and hexopyranosyl; and
 - 13) 7H is missing, i.e. (7H,9H).
- e) Claims 10 and 11 contain hand written text, i.e. in need thereof.
- f) Claim 12 is vague and indefinite in that there is no definition for the variable R₃ in the structure of formulae III, IV, V and VI.

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- g) Claim 12 recites the limitation " $-(CH_2)_n-Ar$ or $-C(=O)-Ar$ " in the definition of B. There is insufficient antecedent basis for this limitation in the claim.
- h) Claim 13 is vague and indefinite in that there is no definition for the variables R_2 and R_3 in the structure of formulae IV, V and VI.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

- 3. Claims 1-5 and 7-11 are rejected under 35 U.S.C. 102(a) as being anticipated by Phan et al., WO 99/21871. Phan teaches the compounds, compositions and method of use of the instant invention where A is nitrogen; R, R_1 and R_2 are hydrogen; Hal is F, Cl or Br; and Z is hydrogen or $-C(=O)$ -phenyl. See examples 1-3.
- 4. Claims 1-5 and 7-11 are rejected under 35 U.S.C. 102(e) as being anticipated by Phan et al., U.S. 6,124,269. Phan teaches the compounds, compositions and method of use of the instant invention where A is nitrogen; R, R_1 and R_2 are hydrogen; Hal is F, Cl or Br; and Z is hydrogen or $-C(=O)$ -phenyl. See examples 1-3.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-5 and 7-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Phan et al., U.S. 6,124,269 and WO 99/21871. The generic structure of Phan encompasses the instantly claimed compounds (see Formula I, column 2 of U.S. '269) and for the same uses (see column 1) as claimed herein. Examples 1-3 differ only in the nature of the R^p and X substituents. Column 2, line 57 defines the substituent X as F, Cl, Br or I and line 56 defines the substituent R^p as hydrogen or a hydroxy protecting group, where the hydroxy protecting group is as defined in line 66 in column 5 through line 12 in column 6 and in lines 51-55 of column 6. Compounds of the instant invention are generically embraced by Phan in view of the interchangeability of the R^p and X substituents of the [e.g. ketolide ring system]. Thus, one of ordinary skill in the art at the time the invention was made would have been motivated to select for example I for X or acetyl for R^p as well as other possibilities from the generically disclosed alternatives of the reference and in so doing obtain the instant compounds in view of the equivalency teachings outlined above.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to

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identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

6. Claim 6 is rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 5 of prior U.S. Patent No. 6,352,983. This is a double patenting rejection.

7. Claim 6 is provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 5 of copending Application No. 10/302,324. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 1-5 and 7-13 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 and 6-12 of U.S. Patent No. 6,352,983. Although the conflicting claims are not identical, they are

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not patentably distinct from each other because the claims of U.S. 6,352,983 are embraced by the claims of the instant invention when R_3 is hydrogen.

9. Claims 1-5 and 7-12 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 and 6-12 of copending Application No. 10/302,324. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of copending Application No. 10/302,324 are embraced by the claims of the instant invention where R_3 is hydrogen.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda Coleman whose telephone number is 571-272-0665. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 571-272-0674. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Brenda Coleman

Brenda Coleman
Primary Examiner Art Unit 1624
May 3, 2004